

07-21-06

1FW



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Egbertson et al.

Serial No.: 10/500,972

Docket No.: 21021YP

Filed: July 2, 2004

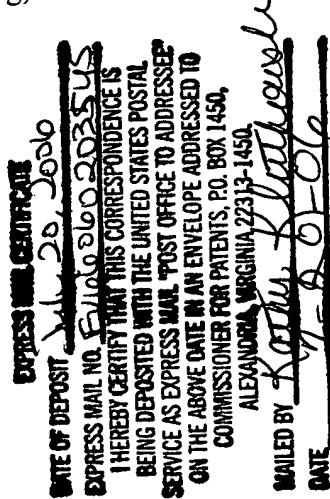
For: HYDROXYNAPHTHYRIDINONE CARBOXAMIDES
USEFUL AS HIV INTEGRASE INHIBITORS

Art Unit:

1626

Examiner:

Chung, Susannah Lee



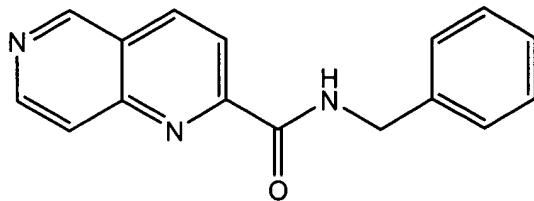
Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

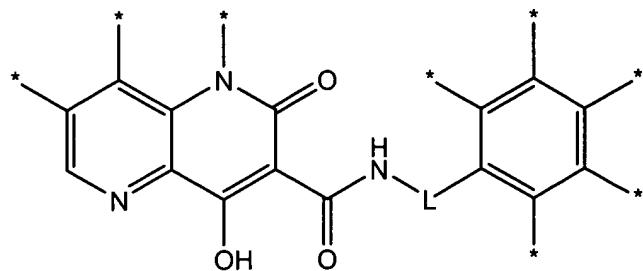
Sir:

This communication is in response to the Office Action mailed June 21, 2006 which set a one-month period for response that expires on July 21, 2006. Claims 1-20 are pending. The Examiner has required restriction under 35 U.S.C. § 372, but has failed to set forth a precise listing of inventive groups. She has instead list only "exemplary" groups, alleging a precise listing cannot be made. Given the inherent ambiguity of the restriction requirement, it is difficult to make an election. The Examiner has recognized this and has stated that the applicant may formulate and elect a group not listed in the exemplary groups. Accordingly, claims 1-20 drawn to products, pharmaceutical compositions and methods of using the compound of Formula I to treat HIV/AIDS in which L is C₁₋₆ alkyl is elected with traverse.

The Examiner asserts that the claims lack unity of invention because the technical feature of the instant claims does not define a contribution over the prior art. Compound 2 in column 27, Table 1 of Jin et al. is cited in support of this assertion. The Examiner's argument has no merit whatsoever, because the genus and species compounds disclosed in Jin et al. lie completely outside the scope of the instant claims. The Jin et al. compound cited by the Examiner is:



whereas the core of the compound of Formula I claimed in this application is:



There are several differences including:

- (i) The claimed compounds are 1,2-dihydro-1,5-naphthyridines, whereas the Jin et al. compound is a 1,6-naphthyridine.
- (ii) The claimed compounds require a carboxamide substituent in the 3-position of the dihydronaphthyridine ring (i.e., it is not adjacent to a naphthyridine nitrogen) whereas the Jin et al. compound has its carboxamide substituent in the 2-position of the naphthyridine ring (i.e., it is adjacent to a naphthyridine nitrogen).
- (iii) The claimed compounds require an oxo substituent in the 2-position and an OH substituent in the 4-position of the dihydronaphthyridine ring, whereas the Jin et al. compound has neither an oxo nor an OH substituent.

Thus the compounds defined in the claims have a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, which means the claims have unity of invention.

Assuming strictly for the sake of argument that the claims lack unity of invention (they do not), there is no serious burden in conducting a search of all the compounds embraced by Formula I in the same application. The Examiner asserts that the "sheer volume" and the "vastness" of the claimed subject matter makes it a burden to search all of the compounds. Applicants completely disagree. All of the claimed compounds have the same structural core; i.e., they are all 2-oxo-1,2-dihydro-1,5-naphthyridine-3-carboxamides. It is both possible and eminently sensible to search on all the compounds in this application, because any reasonably comprehensive search for information relevant to one group of compounds with this core would inevitably require a search of and result in information relevant to compounds with the same core but pigeon-holed in different groups. Simply put, there would be so much overlap in the

searches that it would be far more efficient to conduct a single search in this application than to conduct essentially the same search in 4 separate applications. As the Examiner surely knows, given the well-defined core, the claimed compounds can be searched at all once and efficiently using the sub-structure search capability available on commercial databases (e.g., Chemical Abstracts and Registry on STN). There is no undue burden.

In view of the above remarks, withdrawal of the restriction requirement is requested.

Request for Corrected Filing Receipt

The filing receipt mailed February 9, 2005 contains an error. One of the joint inventors was omitted from the filing receipt. The inventor who should be added is H. Marie Langford of Lansdale, PA. This inventor is included in the Declaration and is also listed on the return post card acknowledging receipt of the application by the Patent Office. This is the third request for a corrected filing receipt. A copy of the second request (which includes a copy of the first request) is attached hereto as Exhibit 1.

Request for Corrected Patent Application Publication

It is also noted that H. Marie Langford is not listed as an inventor in US2005/0119482 A1, which is the published version of the instant application. If possible, it is requested that the patent application publication be corrected to include H. Marie Langford in the list of inventors. A copy of the first page of the published application with the requested change is attached hereto as Exhibit 2.

Respectfully submitted,

By: 

Kenneth R. Walton

Kenneth R. Walton, Reg. No. 32,951
Attorney for Applicants
MERCK & CO., Inc.
P.O. Box 2000
Rahway, New Jersey 07065-0907
Tel.: (732) 594-3462

Date: July 20, 2006